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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,052	04/05/1999	SHUJI SAITOH	981167	1182

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EXAMINER
HINES, JANA A

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 11/19/2002 27

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/147,052	SAITOH ET AL.	
	Examin r	Art Unit	
	Ja-Na A Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the corresp ndence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *05 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submissions filed on March 18, 2002 and August 5, 2002 has been entered. Claims 20-26 are under consideration in the office action.

Withdrawal of Rejections

2. The rejection of claims 20-26 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of applicants amendments.

The rejection of claims 20-26 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of applicants amendments.

Response to Arguments

3. Applicant's arguments filed August 5, 2002 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. The rejection of claim 26 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained. Claim 26 is directed to a recombinant live vaccine for anti-fowl Mg infection comprising fusion proteins as effective ingredients against subsequent infection with *Mycoplasma gallisepticum*. However, the instant specification fails to provide any experiments that show that such a vaccine would be effective in protecting against *Mycoplasma gallisepticum*.

Applicants argue that the claims are clearly enabled.

However, it is the examiner's position that example 6 teach a challenge test wherein the results reveal that the 40K-S and 40K-C vaccines could be effective vaccines. However, claim 26 is not limited to the 40K-S or –C vaccines but rather to a more generic version. Because the vaccine art is highly unpredictable and the instant specification fails to provide any information that any fusion protein providing immunity from a *Mycoplasma gallisepticum* infection as previously stated, the rejection is maintained. There are no protocols provided which demonstrate which fusion proteins would be effective in immunization, nor are there any protocols detailing the amount of fusion protein which is needed to mount a sufficient immune response. The art is replete with instances where even well characterized antigens that induce an in vitro neutralizing antibody response fail to elicit in vivo protective immunity for reasons already of record. As such, the art teaches that an antigenic protein does not necessarily result in protection of the recipient. There is no scientific data that any

antigenic protein as claimed will result in protective immunity. Since the claims are drawn to vaccine, it is implied that vaccine will provide protective immunity, however there is no evidence stating such. Therefore, it would require undue experimentation given the fact that the specification is completely lacking in teachings as to fusion proteins with the claimed characteristics and the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The rejection of claims 20-24 under 35 U.S.C. 103(a) as being unpatentable over Sajto et al., (WO 94/23019) in view of Yoshida et al., (Virology 1994 Vol. 200) is maintained.

Applicants argue that Sajto does not provide satisfactory results in vivo and that none of the cited references teach the immunological effects in vivo.

However, it is noted that the features upon which applicant relies, such as testing antigenicity *in vivo,* are not recited in the rejected claims. The antibody-antigen response is not limited to in vivo responses. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies i.e., antigenicity *in vivo* and the prevention of infection are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Even though, antigenicity testing is not recited in the claims, Saito et al., teach the expression with a recombinant virus of a polypeptide modified to such an extent as to exhibit antigenicity equivalent to that of any of the above polypeptides. Thus, Saito et al., teach antigenicity. Furthermore, claims 20-25 are not drawn to the fusion proteins ability to prevent infection, therefore this argument is not persuasive.

Applicants argue that there would have been no motivation to use the teaching of Sajto to prepare another fusion to use against infection by Mg.

However, first it is noted that only claim 26 is drawn to fusion proteins against infection by Mg so this argument is not persuasive against any of the other claims. Second, Applicants already stated in their previous arguments that a person of ordinary skill in the art would readily understand that the antigenic gene/proteins disclosed in the prior art could be used with a reasonable expectation of success, therefore this argument is not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, no more than routine skill would have been required to use the signal polypeptide derived Herpes outer membrane protein from Yoshida et al., (Virology 1994 Vol. 200) with the fusion

protein comprising an outer membrane protein that infects birds and vaccine of Saito et al., (WO 94/23019) because Yoshida et al., teach that the FPV recombinant express the gB-1 gene which can elicit neutralizing antibody and fully protect chickens against challenges with virulent strains of MDV; the FPV recombinant is a good candidate for an MDV vaccine; and that gB is an important target for the host immune response thus providing motivation for inclusion. One of ordinary skill in the art would have clearly been motivated to use the fused polypeptide comprising a signal polypeptide and exchange the signal polypeptide of Saito et al., for the signal polypeptide of Yoshida et al., because of the many beneficial effects Yoshida et al., teach. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent polypeptide since only the expected results are taught. The use of alternative signal polypeptides would have been desirable to those of ordinary skill in the art based on the fact that gB-1 gene elicits neutralizing antibody; fully protects chickens against virulent strains of MDV and it is a good candidate for an MDV vaccine. Therefore, the cited prior art clearly teaches these aspects of the instant claims, thus the rejection is maintained.

7. The rejection of claims 25-26 under 35 U.S.C. 103(a) as being unpatentable over Saito et al., (WO 94/23019) in view of Yoshida et al., (Virology 1994 Vol. 200) and further in view of Yangida et al., is maintained.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention

where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Sajto et al., (WO 94/23019) and Yoshida et al., (Virology 1994 Vol. 200) have been discussed above. Yangida et al., teach recombinant Avipox virus having all or part of cDNA for Newcastle disease virus derived fused proteins. Thus, it would have been obvious at the time of applicants invention to use the recombinant Avipox virus with exogenous DNA as taught by Yangida et al, with the fusion polypeptide of Saito et al., (WO 94/23019) in view of Yoshida et al., (Virology 1994 Vol. 200) because Yangida et al., teach that recombinant Avipoxvirus genes are effective as vaccine and can prevent infections of Avipoxvirus.

New Grounds For Rejection
Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 25-26 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 25-26 are drawn to DNA coding for the fusion protein wherein a first DNA sequence is isolated from Mg and coding for an antigenic protein and a second DNA sequence is isolated from a Marek's disease virus gene coding for outer membrane protein wherein coding for antigenic protein and signal polypeptides of claim 20.

The written description of antigenic proteins and signal polypeptides not described by their DNA sequences is not commensurate in scope with the claims drawn to DNA sequences isolated from Mg and coding for the antigenic protein of claim 20 and the second DNA sequence coding for the signal polypeptide of claim 20.

Furthermore, it is unclear how to define DNA sequences isolated from Mg and coding for the antigenic protein of claim 20 and the second DNA sequence coding for the signal polypeptide of claim 20. Neither the claims nor the specification teach DNA sequences isolated from Mg and coding for the antigenic protein of claim 20 nor a second DNA sequence coding for the signal polypeptide of claim 20 when claim 20 does not teach any sequences. Moreover there is no teaching of such DNA sequences. It should be noted that the molecular weight or protein name description is not equivalent to determining a DNA sequence. Furthermore, a protein sequence does not described nor enable the claimed DNA sequences.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the

'written description' inquiry, *whatever is now claimed.*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115). The skilled artisan cannot envision the detailed structure of the DNA sequences isolated from Mg and coding for the antigenic protein of claim 20 and the second DNA sequence coding for the signal polypeptide of claim 20, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Furthermore, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, usually defined by a nucleotide sequence, falling within the scope of the claimed genus. At section B(1), the court states that "An adequate written description of a DNA...'requires a precise definition, such as by structure, formula, chemical name, or physical properties', not a mere wish or plan for obtaining the claimed chemical invention".

Therefore the claims drawn to DNA sequences isolated from Mg and coding for the antigenic protein of claim 20 and the second DNA sequence coding for the signal

polypeptide of claim 20, do not meet the full breadth of the claims within the written description provision of 35 USC 112, first paragraph.

10. Claims 25-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 25 and 26 recite a first and second DNA sequence of claim 20, however claim 20 does not recite a first or second DNA sequence. Neither does claim 20 teach DNA sequences coding for the antigenic proteins or the signal polypeptide. It is unclear how to define the coding sequences since no coding sequences have been recited. Therefore, the metes and bounds of the claim cannot be ascertained. Therefore the claims are rejected.

Claims 25-26 recites the limitation a first and second DNA sequence of claim 20. There is insufficient antecedent basis for this limitation in the claim.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

November 6, 2002

IVAN R. F. SMITH
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